

EPA JACKET for REG. # 74530-60

PROCESSING REQUEST

Reg #: 74530-60

Decision #: 492572

Description: New end-use herbicide product

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated: 01/30/2015

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☒ New CSF(s) Dated: 08/18/2014

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Beth Benbow

Division: RD

Phone: 347-8072

Date: 02/04/2015



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

74530-60

01/30/2015

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ZONE Herbicide

Name and Address of Registrant (include ZIP Code):

Mr. Bert Volger, Agent for
Helm Agro US, Inc.,
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Continued on page 2

Signature of Approving Official:

Kathryn V. Montague, Product Manager 23
Herbicide Branch,
Registration Division (7505P)

Date:

01/30/2015

2. You are required to comply with the data requirements described in the DCI identified below:

Chlorimuron GDCI-128901-1136

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No. 74530-60."
 - Assure that the net contents and EPA establishment number are added to the final printed labeling.
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/18/14

If you have any questions, please contact Beth Benbow at (703) 347-8072 or Benbow.bethany@epa.gov.

Attachment



MASTER LABEL

ACCEPTED

01/30/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 74530-60

Groups **14 + 2** **Herbicide**

ZONE HERBICIDE

ACTIVE INGREDIENTS:	% BY WT.
Sulfentrazone	62.2%
Chlorimuron Ethyl	7.8%
OTHER INGREDIENTS:	30.0%
TOTAL	100.0%

ZONE HERBICIDE contains 0.7 lb active ingredient per pound product (0.62 lb ai/lb of sulfentrazone and 0.08 lb ai/lb of chlorimuron ethyl)

EPA Reg. No. 74530-xxx

EPA Est. No xxx-xx-xxx

Net Contents:

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

- **If Swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
- **If in Eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
- **If on Skin or Clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
- **If Inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

Manufactured for: HELM AGRO US Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610
info@helmagro.com

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Causes moderate eye irritation. Do not get into eyes, on skin, or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt, long pants and protective eyewear
- Shoes plus socks
- Waterproof gloves

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do Not Reuse Clothing. Follow manufacturer's label instructions for cleaning/maintaining PPE. In the event there are no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROL STATEMENTS

Handlers using enclosed cabs or closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR part 170.240 (d)(4-6)], may reduce or modify the handler PPE requirements as specified in the WPS.

PHYSICAL/CHEMICAL HAZARDS

Do not mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur.

USER SAFETY RECOMMENDATIONS

Users should: Always wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to marine/estuarine invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to terrestrial and aquatic plants in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

Surface Water Advisory: Sulfentrazone can contaminate surface water through spray drift. Under some conditions, sulfentrazone may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several too many months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, and areas overlying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-lying tile drainage systems that drain to surface waters.

Ground Water Advisory: This chemical is known to leach through soil into groundwater under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Do not use on coarse soils classified as sand which have less than 1% organic matter.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area at the time of application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal or cleaning of equipment.

Pesticide Storage and Disposal

Store product in original container only. Keep container closed when not in use, away from food or feed, fertilizer and other pesticides. Store in a cool dry place and avoid excess heat. Do not store below 30°F degrees.

Wastes resulting from the use of this product that cannot be used should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, State or local procedures. For more information contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

Container Disposal

Nonrefillable container - Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: (For containers greater than 5 gallons) Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For containers 5 gallons or less) Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Triple rinse (or equivalent). Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Containers - Refill this container with ZONE HERBICIDE only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: Coveralls over long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks.

Prior to using ZONE HERBICIDE, consideration should be given to crop rotation plans. Crops other than soybeans may be extremely sensitive to low concentrations of ZONE HERBICIDE remaining in the soil the next planting season. Choice of rotation crop is restricted following application of ZONE HERBICIDE. (See "ROTATIONAL CROP GUIDELINES" for your geographical region.)

IMPORTANT TO OBSERVE THE FOLLOWING

Do not apply or drain or flush equipment on or near desirable trees or other plants, or on areas where their roots may extend, or in locations where the chemical may be washed or moved into contact with their roots. Injury or loss of desirable trees or vegetation may result. Do not use on lawns, walks, driveways, tennis courts or similar areas. Prevent drift of spray to desirable plants. Keep from contact with fertilizers, insecticides, fungicides and seeds during storage. Do not contaminate any body of water.

Thoroughly clean ZONE HERBICIDE from application equipment immediately after use and prior to spraying crops other than soybeans. Injury may result to subsequent crops if failure to remove even small amounts of ZONE HERBICIDE from application equipment.

Proper Handling Instructions: Do Not mix or load this product within 50 feet of any well to include abandoned and drainage wells, streams and rivers, lakes and reservoirs. This 50 feet perimeter does not apply to capped or plugged wells. It does not apply to dikes that are properly constructed around mixing or loading areas.

Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Any such pad used for this purpose must be constructed to be able to contain: Product spills – Equipment leaks – equipment rinsate or wash – container leaks – rain water that collects on the pad. This pad must be self-contained. Pads that are constructed with roofs must be able to provide a minimum containment capacity of 100%. Pads without roofs must have a capacity to contain a minimum of 110% capacity of the largest container or application equipment that may be on the pad. The above mentioned minimum containment capacities do not apply to equipment/vehicles that are delivering pesticide shipments to the loading or mixing site. Always check with your state regulatory official since each state may have different or additional well set-backs and or containment operation guidelines.

This product must be used in a way to prevent any back siphoning into wells. It must be used in a manner to prevent spills, improper disposal of pesticide, rinsates and or spray mixtures into wells or any water source.

PRODUCT INFORMATION

ZONE HERBICIDE is a dispersible granule formulated to easily mix with water, to be sprayed for selected pre-emergent and pre-plant incorporated weed control in soybeans. Control of many broadleaf weeds and partial control of annual grasses will be attained when applied according to label instructions.

Rainfall or sprinkler irrigation is required to activate Pre-emergence and Pre-plant incorporated applications of ZONE HERBICIDE. The control and duration of effect depend on the following: Use rate, growing conditions at and following time of treatment, weed spectrum, soil pH, moisture and precipitation and organic matter. Use information which is applicable to all ZONE HERBICIDE use geography can be found within the label.

ROTATIONAL GUIDELINES FOR ALL ZONE HERBICIDE APPLICATIONS

The table below describes the minimum length in months from the time of ZONE HERBICIDE application until ZONE HERBICIDE treated soil can be replanted to the crops listed in the table. When a recommended tank mix is used, consult the tank mix partner labels for re-cropping instructions and follow the directions that are most restrictive.

ROTATIONAL GUIDELINE

For Full Use Rates (See Rate Table 1)

Refer to importance of soil pH section on page 8 for additional information

Crop	Rotation Interval A IN, OH, MO, IL, KS, NE, OK Soil pH less than 7.2, (If soil pH is greater than 7.2 use rotation interval B)	Rotation Interval B AL, AR, GA, KY, LA, MI, MS, MO Bootheef, NC, PA, SC, TN, and TX where soil pH is greater than 6.8 (For those states listed above, if soil pH is less than 6.8 use rotation interval A)
	Recropping Interval in Months	Recropping Interval in Months
Soybeans ³	Anytime	Anytime
Wheat, Barley, Rye	4	4
Oats	12	18 ⁴
Alfalfa	12	18
Rice	10	18
Tobacco	10	18
Tomato (transplant)	12	18
Field Corn ¹	10	10
Dry Beans	12	18
Clover, Cotton, Cucumber, Flax, Peanuts, Pumpkin, Sunflower, Popcorn, Sweet Corn, Watermelon, Cabbage, Lentils, Mustard	18	18
Canola (rapeseed), Carrot, Onion, Potato, Sugar Beets and any other crop not listed	36	36

ROTATIONAL GUIDELINE

For Reduced Use Rates – (See Rate Table 2)

Refer to Importance of soil pH section on page for additional information

Crop	Rotation Interval A All States, all pH's except those listed in column B	Rotation Interval B DE, IA, MD, MI, MN, NJ, VA, WI, WV soil pH greater than 6.8
	Recropping Interval in Months ⁴	Recropping Interval in Months ⁴
Soybeans ³	Anytime	Anytime
Wheat, Barley, Rye	4	4
Oats	12	18
Alfalfa	12	18
Rice	10	18
Sorghum	10	18
Tobacco	10	18
Tomato (transplant)	12	18
Field Corn ¹	10	10
Dry Beans	12	18

Clover, Cucumber, Flax, Pumpkin, Sunflower, Sweet Corn, Popcorn, Watermelon, Cabbage, Lentils, Mustard	18	18
Canola (rapeseed), Carrot, Onion, Potato, Sugar Beets and any other crop not listed	36	36
Cotton ²	18 or 12	18 or 12
Peanuts	12	18

Under rotational interval A of the Reduced Rate Table above, a pre-emergent application of a Chlorimuron ethyl product is not allowed in the states of AL, AR, GA, KY, LA, MO, Bootheel, MS, NC, OK, SC, TN and TX where soil pH is greater than 7.0.

Do not use full use rates in the states of DE, IA, MD, MI, MN, NJ, VA, WI and WV.

¹Field corn includes corn grown for grain, silage, and seed corn.

²Cotton may be planted after 12 months where ZONE HERBICIDE was applied at rates of 5 oz/acre or less and meets the following conditions:

- Medium and fine soils
- pH < 7.2
- Rainfall or irrigation must exceed 15" after application of ZONE HERBICIDE to rotate to cotton

³Do not feed treated soybean forage or soybean hay to livestock.

⁴Crops that have rotational intervals greater than 12 months after an ZONE HERBICIDE application are the result of crop injury concerns. The crops should be planted with a successful bioassay.

BIOLOGICAL ACTIVITY

ZONE HERBICIDE quickly inhibits growth of susceptible weeds. Susceptible weeds may germinate and emerge following an application of pre-plant incorporation or pre-emergence treatment, but leaves become yellow 3-5 days after emergence and growth ceases. Death of growing points and leaf tissue will occur in some species while others will remain green, stunted and non-competitive. ZONE HERBICIDE will provide partial control of some annual grasses applied correctly but an additional product(s) may be warranted to provide best grass control.

Seedling vigor may be impacted if poor growing conditions prevail. If poor growing conditions are present ZONE HERBICIDE (like other soil applied herbicides) may injure soybeans. In the event injury symptoms appear they will disappear rapidly and will not result in reductions of yield. Poor growing conditions, such as cool temperatures, presence of disease pathogens, excessive moisture and soil compaction may cause this temporary injury to soybeans.

WEEDS CONTROLLED-PREEMERGE

When used as directed ZONE HERBICIDE will provide control of the following weed species:

Carpetweed	Russian Thistle
Cocklebur*	Nutsedge, Purple
Copperleaf, Hophornbeam	Nutsedge, Yellow
Copperleaf, Virginia	Pigweed
Florida beggarweed	Palmer amaranth
Jimsonweed	Redroot
Kochia	Smooth
Lambsquarters	Spiny amaranth
Mallow, Venice	Poinsettia, wild
Marestail	Prickly sida (teaweed)
Morningglory	Purslane, common
Annual	Ragweed, common
Ivyleaf	Ragweed, giant*
Entireleaf	Senna, Coffee
	Smartweed (annual)

Pitted Smallflower Tall	Spurge, Spotted Sunflower, wild
Mustard, wild	Velvetleaf
Nightshade, Black	Waterhemp, common
Nightshade, Eastern Black	Waterhemp, tall
Nightshade, Hairy	Star of Bethlehem

*Weed species which can germinate deep in the soil such as pitted morningglory, cocklebur, and giant ragweed or other weeds; such as nutsedge, which may emerge at various times during the growing season may require a cultivation or a follow up application of postemergence herbicides for season-long control.

ZONE HERBICIDE will provide partial control of the following weeds when used as directed:

Barnyardgrass	Mexicanweed
Burcucumber	Panicum Texas and fall
Crabgrass	Sesbania, Hemp
Foxtail, species	Sicklepod
Goosegrass	Signalgrass, broadleaf
Johnsongrass, seedling	

For additional instructions on weed control, see comments following **Rate Table 1**.

APPLICATION GUIDELINES

SPRAY VOLUMES

Ground Application: Apply uniformly by ground equipment with a properly calibrated sprayer equipped with fan-type nozzles or other appropriate nozzles. Adjust spray pressures to recommendations that are appropriate for the nozzle type being utilized. Sprayer and spray nozzles should be set to minimize the risk of fine droplets (<150 microns), yet achieve adequate coverage of existing weeds. Use nozzles that require screens no finer than 50 mesh. Use 10 to 40 gals of water per acre.

Continuous agitation in the spray tank is required to keep the product in suspension. Avoid overlap and shut off spray booms while starting, turning, slowing or stopping, as injury to the crop may result.

Aerial Application: ZONE HERBICIDE may be applied by air using properly calibrated nozzle types and arrangements that will provide optimum coverage while producing minimal amounts of fine droplets. Apply sufficient spray volume to achieve adequate coverage. Apply a minimum of five (5) gallons of finished spray per acre. Do not apply when wind speed favors drift beyond the area intended for treatment.

PREPARATION OF SPRAY TANK

Before using ZONE HERBICIDE it is very important the spray equipment is clean and free of any previous pesticide deposits in the tank. Use the previous product's label that was used and follow Tank Cleanout procedures that are on the label. If no procedure is provided use the cleanout procedure on the ZONE HERBICIDE label marked SPRAYER CLEANOUT.

Mixing Instructions

1. Fill the tank 1/4 to 1/3 full of water.
2. Add the required amount of ZONE HERBICIDE while agitating.
3. Maintain agitation and continue filling tank with water to insure ZONE HERBICIDE is fully dispersed.
4. Before adding any other material ZONE HERBICIDE should be thoroughly mixed with water in the spray tank. Mixing order should be the following: Fill tank half-full and add ZONE HERBICIDE – while continue filling with water add other herbicide(s), recommended spray adjuvant and liquid nitrogen fertilizer if recommended.
5. Apply ZONE HERBICIDE spray solution within 24 hours of mixing to avoid product degradation.
6. If spray tank has stopped and the mixture has settled, before using re-agitate thoroughly.
7. When tank mixing with liquid fertilizers always prepare a slurry with water before adding to spray tank.

SPRAYER CLEANOUT

To avoid injury to desirable crops, thoroughly clean all mixing and spray equipment immediately following applications of ZONE HERBICIDE as follows:

1. Drain tank; thoroughly hose down the interior surfaces of the tank; then flush tank, boom, and hoses with clean water for a minimum of 5 minutes.
2. Fill spray tank half full of water and add one of the cleaning agents listed below. Finish filling the tank with water, and then flush the cleaning solution through the boom, hoses, and nozzles. Add water to completely fill the tank and allow to agitate or recirculate for at least 10 minutes. Again, flush the boom, hoses and nozzles, and drain the tank.
3. Remove the nozzles and screens and clean separately in a bucket containing water and the cleaning agent.
4. Repeat Step 2.
5. Thoroughly rinse the tank with clean water for a minimum of 5 minutes, flushing water through the boom-nozzles and hoses.

NOTE: Carefully read and follow the individual cleaning agent instructions. Use any of the following cleaning agents:

- One gallon of household ammonia (contains 3% active) per 100 gallons of water.
- Commercial spray tank cleaner

Do not drain or flush equipment on or near desirable trees or plants.

Do not contaminate any body of water including irrigation water that may be used on other crops.

Should small quantities of ZONE HERBICIDE remain in inadequately cleaned mixing, loading, and/or spray equipment, they may be released during subsequent applications potentially causing effects to certain crops and other vegetation. Helm Agro accepts no liability for any effects due to inadequately cleaned equipment.

IMPORTANCE OF SOIL PH

Always determine soil pH by laboratory analysis using a 1:1 ratio of soil to water suspension.

Variations of soil pH in the same field can vary as much as 2 pH units is not uncommon. Therefore, it is recommended that subsampling for pH values that may be higher than a field average. Do not depend on composite soil samples taken for analysis of soil fertility since they may not detect areas of high pH.

The following is a non-inclusive list of potential high pH areas where sub-sampling is recommended:

- Where different soil types are evident within a field, sample soil types separately.
- Where conditions vary within a field, sample areas separately, such as:
 - areas bordered by limestone gravel roads,
 - river bottoms subject to flooding,
 - low areas in hardpan soils where evaporative ponds may occur,
 - eroded hillsides,
 - along drain tile lines, and
 - areas where drainage ditch spoil has been spread.
- Where lime has not been deeply incorporated, soil may exhibit significantly higher pH values in the upper 3 inches of soil. Composite soil samples taken at a 6-8 inch depth may not reflect the elevated pH near the surface. In these cases shallow sampling, the upper 3 inches, is advised.

SPRAY DRIFT MANAGEMENT

AVOIDING SPRAY DRIFT IS THE RESPONSIBILITY OF THE APPLICATOR. Factors relating to the potential for spray drift are many. The most common is the interaction of many equipment and weather-related factors that can determine potential spray drift. Ultimately it is the applicator who is responsible for taking all these factors into consideration when making decisions on applications.

Importance of Droplet Size

APPLYING LARGER DROPLETS REDUCES SPRAY DRIFT POTENTIAL, BUT IT WILL NOT PREVENT DRIFT IF APPLICATIONS ARE MADE IMPROPERLY OR MADE UNDER UNFAVORABLE ENVIRONMENTAL CONDITIONS. Droplet sizes >150-200 microns applied in a spray is the most effective way to reduce the

potential for spray drift. This is the best strategy to manage the potential for spray drift and is based upon larger droplets to provide better coverage and control. Factors that also can affect an applicator's decision on balancing drift control and coverage are: the presence of non-targeted crops nearby – environmental conditions – and pest pressures.

Controlling Droplet Size- General Techniques

Volume - Nozzles with higher rated flows produce larger droplets.

Pressure - WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE. Use the lower spray pressures recommended for the nozzle. Higher pressure reduces droplet size and does not improve canopy penetration and deposition.

Nozzle Type - With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Use a nozzle type that is designed for the intended application.

Boom Height

Setting the boom at the lowest labeled height (if specified) which provides uniform coverage reduces the exposure of droplets to evaporation and wind. For ground equipment, the boom should remain level with the crop and have minimal bounce.

EFFECTS ON DRIFT POTENTIAL BY – WIND – TEMPERATURE AND HUMIDITY TEMPERATURE INVERSIONS

Wind

Drift potential increases at wind speeds of more than 10 mph or less than 3 mph (due to inversion potential). However, many factors, including droplet size and equipment type determine drift potential at any given wind speed. AVOID GUSTY OR WINDLESS CONDITIONS.

Temperature Inversions

Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Drift potential is high during a temperature inversion. Temperature inversions are common on nights with limited cloud cover and light to no wind and are characterized by increasing temperature with altitude. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Temperature and Humidity

When making applications in hot and dry conditions, set up equipment to produce larger droplets to reduce effects of evaporation.

RESISTANCE MANAGEMENT

When herbicides with the same mode of action are used repeatedly over several years to control the same weed species in the same field, naturally-occurring resistant weed biotypes may survive a correctly applied herbicide treatment, propagate, and become dominant in that field. These resistant weed biotypes may not be adequately controlled. Cultural practices such as tillage, preventing weed escapes from going to seed, and using herbicides with different modes of action within and between crop seasons can aid in delaying the proliferation and possible dominance of herbicide resistant weed biotypes. Consult your local company representative, state cooperative extension service, professional consultants or other qualified authorities to determine appropriate actions for treating specific resistant weeds.

Best Management Practices

Proactively implementing diversified weed control strategies to minimize selection for weed populations resistant to one or more herbicides is recommended. A diversified weed management program may include the use of multiple herbicides with different modes of action and overlapping weed spectrum with or without tillage operations and/or other cultural practices. Research has demonstrated that using the labeled rate and directions for use is important to delay the selection for resistance. Scouting after a herbicide application is important because it can facilitate the early identification of weed shifts and/or weed resistance and thus provide direction

on future weed management practices. One of the best ways to contain resistant populations is to implement measures to avoid allowing weeds to reproduce by seed or to proliferate vegetatively. Cleaning equipment between sites and avoiding movement of plant material between sites will greatly aid in retarding the spread of resistant weed seed.

IMPORTANT PRECAUTIONS

- All direct or indirect contact (such as spray drift) to other crops or to land scheduled to be planted to crops other than soybeans should be avoided.
- Soybean stunting may occur if excessive rainfall occurs after application but before soybeans emerge. Injury is more prevalent under poor drainage or compacted conditions or when soil is saturated for long periods of time. Soybeans rapidly outgrow stunting once favorable growing conditions return.
- Seedling disease, nematodes, cold weather, deep planting (more than 2"), excessive moisture, high salt concentration, or drought may weaken soybean seedlings and increase the possibility of crop injury.
- Back to back application of ALS or ALS containing herbicides can occasionally result in residual herbicide stacking and potential crop injury. Grower should be aware of previous herbicide use and potential interaction it may have with ZONE HERBICIDE application.
- Thoroughly clean ZONE HERBICIDE from application equipment immediately after use and prior to spraying crops other than soybeans. Failure to remove even small amounts of ZONE HERBICIDE from application equipment may result in injury to subsequently sprayed crops.

USE RESTRICTIONS

- Apply ZONE HERBICIDE according to Rate Tables 1 or 2 as directed for specific types of application and geographic areas. Do not use the full use rate (Rate Table 1) in DE, IA, MD, MI, MN, NJ, VA, WI and WV.
- Do not use ZONE HERBICIDE in CO, WY, ND, NY or SD at any rate. Do not apply ZONE HERBICIDE in Nebraska west of US Hwy 281 and north of US Hwy 30.
- Do not apply to black belt soil of Alabama or Mississippi with a soil pH >6.8 or history of nutrient deficiency such as iron chlorosis, as injury may occur.
- Do not follow ZONE HERBICIDE with a post-emergence application of another chlorimuron-ethyl containing herbicide in the same cropping season.
- Do not apply ZONE HERBICIDE if there are visible signs of cracking due to soybean emergence, or serious crop injury may result.
- Do not apply or drain or flush equipment on or near desirable trees or other plants, or on areas where their roots may extend, or in locations where the chemical may be washed or moved into contact with their roots, or injury to desirable trees and plants may occur.
- Do not use on lawns, walks, driveways, tennis courts or similar areas. Prevent drift of spray to desirable plants. Do not contaminate any body of water. Keep from contact with fertilizers, insecticides, fungicides and seeds during storage.
- Do not tank mix ZONE HERBICIDE with organophosphate insecticides. Do not apply ZONE HERBICIDE within 14 days before or after an application of an organophosphate insecticide, as severe crop injury may occur.

Follow all label restrictions regarding soil type, soil pH, organic matter, rotational crop intervals, geographic location, and weed pressure, in selecting the rate of ZONE HERBICIDE from Rate Table 1 or Table 2.

Use of ZONE HERBICIDE on soils which exceed pH 6.8 may result in unacceptable injury to the following crop. ZONE HERBICIDE may be used on fields which are generally pH 6.8 or less, but which may contain isolated areas where the pH exceeds 6.8 only if the following rotational crop is soybeans or a Helm Agro recommended chlorimuron ethyl resistant corn variety.

ADDITIONAL USE RESTRICTIONS (For Use on Soybeans)

- Do not apply this product through any type of irrigation system.
- Do not feed treated soybean forage or soybean hay to livestock.
- Single application: Do not apply a full rate of ZONE HERBICIDE more than once per season.
- Split application: Two applications totaling the full labeled rate of ZONE HERBICIDE (see Table 1) may be made per season.

- Do not apply ZONE HERBICIDE after the soybean crop has emerged or severe injury or death of the crop may occur. ZONE HERBICIDE may be applied by any of the methods listed below.

Full Use Rate

Rate Table 1: Fall application, Early Pre-plant, Pre-plant Burndown, Pre-plant Incorporated, and Pre-emergence: No-Till, Minimum-till, Conventional tillage

Soil Texture	Organic Matter	
	0.5 – 2%	2 – 4%
	Ounces Product (lb a.i.) Per Acre	
Coarse: Loamy Sand, Sandy Loam	5.0(0.219) – 6.0(0.263)	6.0(0.263) – 7.0(0.306)
Medium: Loam, Silt Loam, Silt, Sandy Clay Loam	6.5(0.284) – 7.5(0.328)	7.0(0.306) – 8.0(0.350)
Fine: Silty Clay Loam, Clay Loam, Clay	7.0(0.306) – 8.0(0.350)	8.0(0.350) – 9.6(0.420)

Apply ZONE HERBICIDE according to Rate Tables for types of application and specific geographic areas.

Reduced rate for GMO soybean (Roundup Ready, Liberty Link)

Rate Table 2: Use rates in Table 2 are to be used in conjunction with a planned POST herbicide program; ZONE HERBICIDE at these reduced rates will provide early season control or suppression to reduce early season weed competition.

Fall application, Early Pre-plant, Early Pre-plant Burndown, Pre-plant Incorporated, Pre-emergence: No-Till, Minimum-till, Conventional Tillage

Soil Texture	Organic Matter	
	0.5 – 2%	2 – 4%
	Ounces Product (lb a.i.) Per Acre	
Coarse: Loamy Sand, Sandy Loam	3.0(0.131) – 4.0(0.175)	3.2(0.140) – 4.0(0.175)
Medium: Loam, Silt Loam, Silt, Sandy Clay Loam	3.2(0.140) – 4.0(0.175)	3.2(0.140) – 4.8(0.210)
Fine: Silty Clay Loam, Clay Loam, Clay	4.0(0.175) – 5.0(0.219)	4.0(0.175) – 5.0(0.219)

APPLICATION METHODS

Do not apply ZONE HERBICIDE after the soybean crop has emerged or severe injury or death of the crop may occur. ZONE HERBICIDE may be applied by any of the methods listed below.

CONSERVATION TILLAGE

Early Pre-Plant in No-Till, Minimum Till, or Stale Seedbed

ZONE HERBICIDE applied Early Pre-plant must be applied in combination with the appropriate burndown herbicide such as glyphosate, glufosinate, gramoxone, and/or 2,4-D to achieve acceptable control of existing weeds during application. ZONE HERBICIDE is rainfast after one hour when applied as a burndown treatment. For burndown or control of existing vegetation, an appropriate burndown herbicide at labeled rates is recommended such as glyphosate etc. Follow all label directions for the burndown herbicide including application timing, spray volume, adjuvants to achieve control of targeted weeds. For applications of ZONE HERBICIDE made from 30 – 60 days before planting apply the higher rate in the appropriate soil range from

tables 1 or 2 depending on the soybean system being grown.

PRE-EMERGENCE

ZONE HERBICIDE may be applied at planting time or within 3 days after planting, but before seed emergence. ZONE HERBICIDE may be applied alone or in tank mix combinations with other registered soybean herbicides. When applied in tank mix combinations, follow applicable use directions, including application rates, precautions and restrictions of each product in the mixture. The seed furrow should be completely closed and seed covered before any applications of ZONE HERBICIDE.

PRE-PLANT INCORPORATED

Uniformly incorporate ZONE HERBICIDE or ZONE HERBICIDE tank mixes no deeper than 2" prior to planting soybeans. If tank-mixing ZONE HERBICIDE with a companion herbicide, follow all label instructions for proper incorporation of the companion herbicide in the top 2" of soil. Improper incorporation can result in erratic weed control or potential crop injury.

FOR HERBICIDE ACTIVATION RAINFALL REQUIREMENT

Best results are obtained if ZONE HERBICIDE is followed by rainfall or irrigation before weeds germinate. Several small rainfalls of less than 1/4" each are not as beneficial as one large rainfall of 1/2-1". If moisture is not sufficient to activate the herbicide, a rotary hoeing or shallow cultivation should be made after emergence of the crop while weeds are small enough to be controlled by mechanical means.

FALL APPLICATIONS

ZONE HERBICIDE may be applied as a fall treatment to the stubble of harvested crops for the burndown of existing vegetation and pre-emergence control of labeled weeds the following spring in no-till and conservation tillage production systems. If weeds are emerged at the time of application, utilize a tank mixture with a suitable burndown herbicide such as glyphosate, or glufosinate at labeled rates. Fall applied burndown treatments should be made with a minimum of 10 gallons per acre to achieve adequate coverage of the weeds being treated. Applications volume should be increased to 15-20 gallons per acre or more where weed density is high or heavy crop residue levels are present. When making burndown applications to emerged weeds, the addition of adjuvants such as COC, NIS, or MSO to the spray mixture can be used to enhance the burndown activity of the application. Refer to product labels for use rates and instructions. Refer to rates in Table 1 or Table 2. Use the higher rate in the soil type for longer spring residual.

FALL APPLICATION AND SPRING PRE-PLANT BURNDOWN OF BROADLEAF WEEDS

ZONE HERBICIDE may be used as part of burndown program to provide control or suppression of the following broadleaf weeds. For complete control of emerged weeds follow specific directions under the list of weeds below:

Chickweed ¹	Nightshade species
Dandelion	Pennycress
Garlic, wild	Pigweeds
Henbit	Ragweed, common
Lambsquarters	Ragweed, giant
Lettuce, prickly	Shepherd's-purse
Marestail	Smartweeds, annual
Mustard, tansy	Sunflower
Mustard, wild	Waterhemp species

¹For chickweed control add glyphosate or Express or Dicamba.

For Burndown control, pick the appropriate rate from **Rate Table 1 or 2** and apply with:

- For complete burndown of emerged annual grasses or broadleaf weeds or for burndown of weeds not listed above, ZONE HERBICIDE must be tank mixed with: glyphosate, glufosinate, paraquat, 2,4-D or other appropriate burndown herbicides.
- Crop Oil Concentrate (COC) or Methylated Seed Oil (MSO) at 1% v/v 1 gallon per 100 gallons of spray solution, or Non-ionic surfactant (NIS) at 1 qt./100 gallon of spray solution.
- In addition to the specific adjuvants above, other adjuvants may be used if they provide the same or similar functions as those previously mentioned. The addition of other adjuvants or fertilizers such as ammonium sulfate (AMS) may aid in control of weeds when used with appropriate companion herbicides. Consult specific companion herbicides for additional adjuvant, and fertilizer recommendations when applying for burndown of existing vegetation.
- Use flat fan nozzles or other appropriate nozzle types and a minimum of 10 gallons of water per acre. Where dense vegetation or heavy crop residues are present, increasing the spray volume to 15-20 gallons per acre or more may improve spray coverage and weed control.

To select the proper tank mix product, identify the weeds which need to be controlled and consult the product labels to determine which product is needed. Consult the companion tank mix herbicide label for use instructions, rates, precautions, restrictions, and other use information.

For instructions on how to prevent spray drift see section on SPRAY DRIFT MANAGEMENT on page 8.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

Follow Directions for Use of this product carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Helm Agro US, Inc. or Seller. To the extent of applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Helm and Seller harmless for any claims relating to such factors.

Helm warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Helm, and Buyer and User assume the risk of any such use. **HELM MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law, in no event shall Helm or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF HELM AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF HELM OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Helm and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Helm.

Roundup is trademark of Monsanto Technology LLC
Ignite is a trademark of Bayer CropScience



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

10/DEC/2014

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for Zone Herbicide

Subject: Name of Pesticide Product: Zone Herbicide
 EPA File Symbol: 74530-AN
 DP Barcode: D421456
 Decision No.: 492572
 Action Code: R310
 PC Codes: 129081 Sulfentrazone
 128901 Chlorimuron

From: Tracy Keigwin, Biologist
 Chemistry, Inerts and Toxicology Assessment Branch
 Registration Division (7505P)

To: Bethany Benbow
 Herbicide Branch
 Registration Division (7505P)

M. Hashim
Team Leader - Toxicology

Applicant: Helm Agro US, Inc.
 4042 Park Oaks Blvd., Suite 330
 Tampa, FL 33610

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sulfentrazone	62.2
Chlorimuron Ethyl	7.8

<u>Other Ingredient(s):</u>	30.0
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Total: 100.0%

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies submitted in support of EPA File Symbol 74530-AN, Zone Herbicide.

BACKGROUND: Helm Agro US Inc. has submitted an application for the registration of EPA File Symbol 74530-AN, Zone Herbicide. In support of this product, the registrant has submitted the following acute toxicity studies: MRIDs 49417904 (870.1100), 49417905 (870.1200), 49417906 (870.1300), 49417907 (870.2400), 49417908 (870.2500), and 49417909 (870.2600). The product label states that Zone Herbicide is a dispersible granule formulation for selected pre-emergent and pre-plant incorporated weed control in soybeans.

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES/DEVIATIONS: None

COMMENTS AND RECOMMENDATIONS:

1) All 6 studies are acceptable. The acute toxicity profile of EPA File Symbol 74530-AN, Zone Herbicide is as follows:

acute oral toxicity	III	Acceptable	MRID 49417904
acute dermal toxicity	IV	Acceptable	MRID 49417905
acute inhalation toxicity	IV	Acceptable	MRID 49417906
primary eye irritation	III	Acceptable	MRID 49417907
Primary skin irritation	IV	Acceptable	MRID 49417908
dermal sensitization	NO	Acceptable	MRID 49417909

2) The First Aid Statement must be revised so that the most toxic routes of exposure (oral and eye) are listed before dermal and inhalation statements.

3) The Basic CSF (dated June 20, 2014) must be accepted by the product chemistry team before this action is finalized.

The following are the precautionary and first aid statements for this product (next page):

PRODUCT ID #: 74530-AN (74530-60)

PRODUCT NAME: Zone Herbicide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear protective eyewear*, long-sleeved shirt and long pants, socks and shoes. Remove and wash contaminated clothing before reuse.

*Protective eyewear may be worn if appropriate.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Reviewer: Tracy Keigwin
Risk Manager (EPA): 23

Date: December 10, 2014

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 74530-AN:

1. DP BARCODE: 421456				
2. PC CODES: 129081 and 128901				
3. CURRENT DATE: December 10, 2014				
4. TEST MATERIAL: Sulfentrazone +Chlorimuron-ethyl 62.2+7.8 WG (Batch# L1309; PSL Reference Number 130701-8G; Purity: 62.46% Sulfentrazone, 7.89% Chlorimuron; light brown granule; pH: 5.02 (as a 1% w/w solution); Solubility: Soluble in water).				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat PSL (Dayton, NJ) Study #36880/October 4, 2013 OCSPP 870.1100; OECD 425	49417904	LD ₅₀ Females=1750 mg/kg bw. The test material was administered as a 40% w/w mixture in distilled water. At <u>175 mg/kg</u> (1 rat) and <u>550 mg/kg</u> (2 rats) all survived. No clinical abnormalities observed at the 175 mg/kg concentration. One animal exhibited reduced fecal volume at the 550 mg/kg dose level. No other clinical signs observed. No gross abnormalities observed at either dose level at necropsy. At <u>1750 mg/kg</u> (4 rats) 1 animal died within 2 days of test substance administration. This rat exhibited hypoactivity, a hunched posture, irregular respiration and reduced fecal volume prior to death. Of the remaining animals, one animal exhibited hypoactivity, ano-genital staining, and reduced fecal volume, recovering by study day 6. At necropsy the decedent exhibited a distension of the stomach and intestines. No gross abnormalities observed in surviving animals at necropsy. At <u>5000 mg/kg bw</u> (4 rats) all rats died within 2 days of dosing. Prior to death, rats exhibited	III	A

		abnormal posture, hypoactivity, irregular respiration, tremors, reduced fecal volume and/or oral discharge. Decedents exhibited a distension of the stomach or intestines and/or discolored lungs or a mottled liver.		
Acute dermal toxicity / rat PSL (Dayton, NJ) Study #36881/October 14, 2013 OCSPP 870.1200; OECD 402	49417905	LD ₅₀ > 5000 mg/kg (both sexes-5 males and 5 females tested). No deaths. Erythema and/or desquamation was observed in 4/5 females, resolving in all by study day 10. One female lost weight by the day 7 observation, gaining weight thereafter although not surpassing the initial body weight. No other clinical abnormalities observed. No gross abnormalities observed at necropsy.	IV	A
Acute inhalation toxicity / rat PSL (Dayton, NJ) Study #36882/October 31, 2013 OCSPP 870.1200; OECD 403	49417906	LC ₅₀ > 5.17 mg/L (Nose-only, gravimetrically determined; both sexes and combined). Mean MMAD and GSD: 2.61 µm and 2.20, respectively. All survived. All animals exhibited abnormal respiration and were hypoactive following exposure, recovering by study day 3. All animals lost or failed to gain weight by day 1, however, all exceeded their initial weight by study termination (day 14). No gross abnormalities were observed at necropsy.	IV	A
Primary eye irritation / rabbit PSL (Dayton, NJ) Study #36883/October 14, 2013 OCSPP 870.2400; OECD 405	49417907	No iritis observed. Corneal opacity was observed in 1/3 at the 24 hour observation only. Grade 2 chemosis was observed in 1/3 rabbits at the one hour observation only. Tan staining on the fur around the eye noted in all rabbits (3/3) at the 1 hour observation. All scores zero at 48 hours. MMTS = 8.7.	III	A

Primary dermal irritation / rabbit PSL (Dayton, NJ) Study #36884/September 18, 2013 OCSPP 870.2500; OECD 404	49417908	PDI = 0.0 (non-irritating). No erythema or edema observed. No clinical signs observed. PDII = 0.	IV	A
Dermal sensitization (LLNA)/ Mouse PSL (Dayton, NJ) Study #36885/October 2, 2013 OCSPP 870.2600; OECD 429	49417909	Product is <u>not</u> a dermal sensitizer. 5 groups tested – a vehicle control group (1% Pluronic L92 Surfactant w/w in distilled water), a positive control group (25% HCA in 1% Pluronic L92 Surfactant w/w in distilled water), and a test substance group (10%, 25% and 50% test substance in 1% Pluronic L92 surfactant w/w in distilled water). Animals treated with 10%, 25%, and 50% concentrations of the test substance had SI values of 0.87, 0.72 and 1.30, respectively (<3 not considered a positive response). SI value for positive control group (25% HCA) was 5.19 (acceptable).	No	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap



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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: 421455 REG. File Symbol No 74350- AN PRODUCT NAME: ZONE HERBICIDE
PC Code(s):128901, 129081 Decision No. 492572 Action Code: 310 Food Use: Yes [X]

DATE OUT: 11/25/14

SUBJECT: Product Chemistry Review of New End Use Product
Product Name: Zone Herbicide

FROM: Indira Gairola, Product Chemistry Team
CITAB / Registration Division (7505P)

TO: Kathryn Montague / Bethany Benbow PM 23
Herbicide Branch/Registration Division (7505P)

Company Name: Helm Agro US, Inc.
Formulation Type: Herbicide: (granular solid)

INTRODUCTION:

The registrant submitted an application for registration of the new end use product "Zone Herbicide". Registrant has submitted revised Basic CSF dated 08/18/14. Applicant is submitting (MRID #s 494179-01 to -03 for product chemistry data to support this registration application. Applicant claims the subject product to be a "me too" of EPA Reg. No. 279-3413. CITAB has been asked to determine the acceptability of the aforementioned product chemistry data and revised basic CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient (s) Sulfentrazone TC (62.2%), Chlorimuron ethyl TC (7.8%).
2. Has the registrant claimed substantial similarity to a registered product?
[] NO [X] Yes [] NA; if yes give the registration number of the cited product.
EPA Reg. No. 279-3413.
3. All of the source materials of the active ingredient are derived from registered sources-
[] Yes [] No [] [X] Pending Registration
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled food uses. [X] Yes

5. Confidential Statement of Formula(s):

☒ Proposed Basic dated 06/20/14

Resubmitted date 08/18/14

☐ Proposed Alternate:

Proposed Alternate comply with 40CFR§152.43: ☐ Yes; ☐ No ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs. other ingredient?)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☒ NA

Isomeric ratios ☒ NA

Soluble Arsenic ☒ NA

Acid Equivalent ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No; ☒ NA; if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes Explain below:

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid (granular)	A	494179-03
830.6315	Flammability	Does not contain flammable liquid	A	494179-03
830.6314	Oxi/ Red	In compatable with 10% of KmnO4	A	494179-03
830.6316	Explodability	Does not contain explosive ingredients	A	494179-03
830.6320	Corrosion Characteristic	In progress	I	494179-03
830.6317	Storage Stability	In progress	I	494179-03
830.7000	pH	5.02 (1%) soln.@20.1°C	A	494179-03
830.7100	Viscosity	9.9 centistokes at 20°C 4.8 centistokes at 40°C	A	494179-03
830.7300	Density (units)	Pour density0.527g/mL Tap density 0.621 “ “ “	A	494179-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable.

CONCLUSIONS:

CITAB has reviewed resubmitted basic CSF dated 08/18/14 and product chemistry data corresponding to guideline 830 series, group A & group B for the proposed subject product "Zone Herbicide" and concluded:

1. The data corresponding to 830 series group A for the proposed subject product "Zone Herbicide" are acceptable.
2. Product chemistry Data for 830 series group B are acceptable.
3. Applicant has indicated that data for one-year storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies are underway and will be submitted when complete. The results from both study types should include observations at 0, 3, 6, 9, and 12 month intervals.
4. Revised basic CSF dated 08/18/14 is acceptable subject to the acceptance of pending registration of the source products of active ingredients.
5. The subject product cannot be considered as a "me too" of EPA Reg. No. 279-3413, the inerts are different in the subject product as compared to the cited product.
6. The proposed label was screened as it pertains to the product chemistry requirements.
7. The final review of the proposed label and uses are the purview of the PM team.

NOTE TO THE PM

Since the product is incompatible with 10% KMnO₄ please advise the registrant to add the following statement under the heading "Physical and Chemical Hazards"

"Do not mix or allow coming in contact with oxidizing agents Hazardous Chemical Reaction may occur".

Benbow, Bethany

From: Bert Volger <bertvolger@comcast.net>
Sent: Monday, August 18, 2014 4:37 PM
To: Benbow, Bethany
Cc: Montague, Kathryn V.
Subject: RE: ZONE Herbicide; EPA Decision No. 492572; File symbol 74530-AN
Attachments: 140818 Zone Herbicide (74530-xx) basic CSF -resubmitted.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Bethany,

See attached the revised CSF for the subject product following the standard certified limits (upper and lower limits) as specified under 40CFR 158.175 b(2).

Please let me know, if this is acceptable.

Thanks,
Bert

Ceres International LLC
1087 Heartsease Drive
West Chester, PA 19382
Ph. 610-793-3222
bertvolger@ceresinternational.com

From: Benbow, Bethany [mailto:Benbow.Bethany@epa.gov]
Sent: Monday, August 18, 2014 2:27 PM
To: bertvolger@comcast.net
Cc: Montague, Kathryn V.
Subject: ZONE Herbicide; EPA Decision No. 492572; File symbol 74530-AN
Importance: High

Good afternoon Mr. Volger,

I am contacting you in regard to the registration application submitted for the proposed product, ZONE Herbicide on behalf of Helm Agro, Inc.

During the product chemistry technical screen, it was noted that the proposed formulation dated 6-20-14 contains non-standard certified limits for the active ingredient (chlorimuron) and two of the inert ingredients (used as surfactants). In order to use non-standard certified limits, you will need to provide justification for doing so. Alternatively, you may submit a revised formulation using the standard certified limits.

Please provide a response to this deficiency within 10 business days of receipt of this email. Feel free to contact me if you have any questions or concerns.



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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

Screen

DP BARCODE No.: D421455; **FILE SYMBOL No.:** 74530-AN (screen); **PRODUCT NAME:** Zone Herbicide;
DECISION No.: 492572; **PC Code(s):** 128901, 129081; **ACTION CODE:** R310; **FOOD Use:** Yes

DATE OUT: August 15, 2014

SUBJECT: Completeness check screening for technical product "Zone Herbicide"

FROM: Shyam Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

SBM 8/15/14

TO: Bethany Benbow / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Helm Agro US, Incorporation
Formulation Type: Herbicide
Active Ingredient(s): Sulfentrazone TC (62.2%) and Chlorimuron ethyl TC (7.8%)
MRID No(s): 494179-01 to 494179-03

*corrected
CSF 8/15/14
Rec'd SBM
Continue Next week*

CONCLUSION:

Deficiencies: Yes

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All data submitted

Note 1: 830.1750 (certified limits): The registrant has proposed non-standard certified limits for one of the AI (chlorimuron) and two the inert ingredient (used as surfactants) in the formulation. The registrant must provide justifications for proposed nonstandard certified limits or revise the CSF to indicate correct standard certified limits for these ingredients.

Group B: All required data submitted

Note 2: 830.6314 (oxidation/reduction): Incompatible with 10% potassium permanganate

CSF: Basic CSF (dated 06-20-2014)

Note 3: Same as Note 1.

Product label:

Note 4: Since the product was determined to be incompatible with 10% Potassium permanganate, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to me or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in TRB. New Bean is required in case the bean has been closed by TRB. Thank you.



49417900
HELM AGRO US, INC.

4042 Park Oaks Blvd., Suite 330

Tampa, FL 33610

Phone: (813) 621-8846

Fax: (813) 621-0763

www.helmagro.com

Via Courier Delivery

June 23, 2014

U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Ms. Kathryn Montague
Registration Manager (PM - 23)

Subject: ZONE HERBICIDE (EPA-Reg.No.74530 - to be assigned)
Application for new product registration

HELM Agro US Inc. herewith submits an application for a new end-use product registration containing the two active ingredients, sulfentrazone and chlorimuron-ethyl. The composition of this product and proposed use directions for ZONE HERBICIDE are similar (see enclosed label) to those of the existing, registered end-use formulation, Authority XL Herbicide (EPA Reg. No. 279-3413). Therefore, this application is considered a "me-too" registration, which only requires data review of the enclosed acute toxicity and Product Chemistry studies. Otherwise the application relies on existing data as indicated on the enclosed Data Matrix and the "Cite-all Option" under the Selective Method.

The ZONE HERBICIDE formulation contains all EPA approved formulation ingredients (40 CFR §180.910 - tolerance exemption when used pre- and post-harvest). The Precautionary Labeling is based on the enclosed acute toxicity data (see also toxicity summary below), following EPA's Label Review Manual and 40 CFR part 156.

The subject application for registration is supported by the enclosed information and administrative materials:

1. EPA Form 8570-1:
Executed "Application for Pesticide Registration" (OPP Identifier # 259973).
2. Bibliography of Submitted Studies
Copy of the Bibliography of Submitted Studies. This provides an index of study titles and references to EPA data requirements by OPPTS Guideline number.
3. Proposed Label
Five copies of the proposed ZONE HERBICIDE Master label.

5. Study Data

Three copies of each acute toxicity study report (total of 9 volumes).

4. Results of Acute Toxicity Data

The results of the six required acute toxicity studies for the subject formulation are presented below (see Table). The results show that ZONE HERBICIDE is of low acute oral, dermal and inhalational toxicity to rats (Category III or IV). It is non-irritating to the rabbit skin, minimally irritating to the eye, and shows no sensitization potential in the guinea pig. Based on these data, ZONE HERBICIDE is classified as a Toxicity Category III product (Signal word "CAUTION"; see also proposed labeling reflecting these results).

Acute Toxicity Data for ZONE HERBICIDE (see submitted study reports)

Guideline #	Study	Results (MRID)	Category
81-1	LD50 Oral Rat (female)	1,750 mg/kg	III
81-2	LD50 Dermal rat	>5,000 mg/kg	IV
81-3	LC50 4h Inhalation-rat	>5.17 mg/l	IV
81-4	Eye Irritation rabbit	minimally irritating (clearing in < 24 h)	IV
81-5	Skin Irritation rabbit	Non-irritating	IV
81-6	Skin Sensitization Guinea Pig (Buehler Method)	Negative (not a Sensitizer)	N/A

5. Confidential Statement of Formula

One copy of the Confidential Statement of Formula (CSF).

7. Certification with Respect to Citation of Generic Data

An executed EPA form 8570-34 with respect to citation of data.

8. Data Matrix (EPA form 8570-35)

One copy of a data matrix of all previously submitted data (including the generic data submitters) in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public Use). Helm is offering to pay data compensation to those registrants appearing on the most recent, published EPA Data Submitters Lists for sulfentrazone and chlorimuron-ethyl dated March 27, 2014.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 01, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

HELM AGRO US, INC.
4042 PARK OAKS BLVD., SUITE 330
TAMPA, FL 33610

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 25-JUN-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Completion of 21-Day Content Screen

PM- 23

EPA Reg. # (File Symbol) 74530-AN

Decision # D

Data package delivered to
you on 7/3/14.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,



Registration Division's 21-Day Content Team

Memorandum

Date: 7 / 1 / 14

To: 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: July 1, 2014			EPA Reg No./File Symbol: 74530-xx		Page 1 of 4
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610			Product: ZONE HERBICIDE		
Ingredients: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/ 830.1550	Product Identity and Composition	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
61-2/ 830.1600 & 830.1650	Beginning Materials and Formulation Process	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
61-3/ 830.1670	Discussion of the Formation of Impurities	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
62-1/ 830.1700	Preliminary Analysis	N/A	Helm Agro US, Inc.		Not required for end-use product
62-2/ 830.1750	Certified Limits	N/A	Helm Agro US, Inc.	OWN	See submitted CSF
62-3/ 830.1800	Enforcement Analytical Method	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
63-2/ 830.6302	Color	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
63-3/ 830.6303	Physical State	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
63-4/ 830.6304	Odor	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
63-5/ 830.7200	Melting Point	N/A	Helm Agro US, Inc.		Not required for this end-use product
63-7/ 830.7300	Density	N/A	Helm Agro US, Inc.	OWN	Submitted with subject application
63-8/ 830.7840	Solubility	N/A	Helm Agro US, Inc.		Not required for end-use product
63-9/ 830.7950	Vapor Pressure	N/A	Helm Agro US, Inc.		Not required for end-use product
63-10/ 830.7370	Dissociation Constant	N/A	Helm Agro US, Inc.		Not required for end-use product

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: July 1, 2014		EPA Reg No./File Symbol: 74530-xx		Page 2 of 4	
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610		Product: ZONE HERBICIDE			
Ingredient: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/ 830.7550	Octanol/Water Partition Coefficient	N/A	Helm Agro US, Inc.		Not required for end-use product
63-12/ 830.7000	pH	N/A	Helm Agro US	OWN	Submitted with subject application
63-13/ 830.6313	Stability	N/A	Helm Agro US		Not required for this end-use product
63-14/ 830.6314	Oxidation/reduction: Chemical incompatibility	N/A	Helm Agro US	OWN	Submitted with subject application
63.15/ 830.6315	Flammability	N/A	Helm Agro US	OWN	Not flammable; solid product does not contain any combustible liquids
63-16/ 830.6316	Explosibility	N/A	Helm Agro US	OWN	Not explosive based on its chemical/ physical properties, product does reveal bond groupings to be explosive
63-17/ 830.6317	Storage Stability	N/A	Helm Agro US	OWN	New study under way
63-18/ 830.7100	Viscosity	N/A			Not required for this end-use product.
63-19 830.6319	Miscibility	N/A	Helm Agro US		Not required as this product is being diluted in water, not intended to be mixed and applied in petroleum solvents
63-20/ 830.6320	Corrosion Characteristics	N/A	Helm Agro US	OWN	New study under way
63-21/ 830.6321	Dielectric breakdown voltage	N/A	Helm Agro US		Product is not for use in/on/around electrical equipment
81-1/ 870.1100	Acute Oral Toxicity - Rat	To be assigned	Helm Agro US	OWN	Submitted with subject application
81-2/ 870.1200	Acute Dermal Toxicity-Rabbit	To be assigned	Helm Agro US	OWN	Submitted with subject application
81-3/ 870.1300	Acute Inhalation Toxicity-Rat	To be assigned	Helm Agro US	OWN	Submitted with subject application

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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DATA MATRIX

Date: July 1, 2014		EPA Reg No./File Symbol: 74530-xx		Page 3 of 4	
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610		Product: ZONE HERBICIDE			
Ingredient: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
81-4/ 870.2400	Primary Eye Irritation-Rabbit	To be assigned	Helm Agro US	OWN	Submitted with subject application
81-5/ 870.2500	Primary Dermal Irritation-Rabbit	To be assigned	Helm Agro US	OWN	Submitted with subject application
81-6/ 870.2600	Dermal Sensitization in Guinea Pigs	To be assigned	Helm Agro US	OWN	Submitted with subject application
Helm Agro US Inc. is making offers-to-pay to the following companies listed on EPA's Data Submitters list as of March 27, 2014.		EPA Company No.			
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	279	FMC Corporation	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	352	E.I. DuPont De Nemours and Co.	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	2217	PBI Gordon Corp.	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	9688	Chemsico	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	66607	Spray Drift Task Force	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	71755	Agricultural Reentry Task Force	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	73801	Tagros Chemicals India Ltd.	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	73989	FIFRA Endangered Species Task Force	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	75234	Agricultural Handlers Exposure Task Force	PAY	

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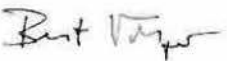
AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION

401 M Street, S.W.
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DATA MATRIX

Date: July 1, 2014		EPA Reg No./File Symbol: 74530-xx		Page 4 of 4	
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610		Product: ZONE HERBICIDE			
Ingredient: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc	82534	Summit Agro North America Holding Corp	PAY	
Sulfentrazone	Cite-All under Selective Method utilized by Helm Agro US Inc.	88783	Summit Agro USA LLC	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	279	FMC Corporation	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	352	E.I. DuPont De Nemours and Co.	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	35935	Nufarm Limited	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	59639	Valent USA Corp.	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	66607	Spray Drift Task Force	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	71368	Nufarm Inc.	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc	71755	Agricultural Reentry Task Force	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	73989	FIFRA Endangered Species Task Force	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	75234	Agricultural Handlers Exposure Task Force	PAY	
Chlorimuron-ethyl	Cite-All under Selective Method utilized by Helm Agro US Inc.	82663	Sharda Cropchem Limited	PAY	
Signature: 			Name and Title: Bert Volger, Ph.D. Agent for HELM AGRO US Inc.		Date: July 1, 2014



49417900
HELM AGRO US, INC.

4042 Park Oaks Blvd., Suite 330

Tampa, FL 33610

Phone: (813) 621-8846

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www.helmagro.com

Via Courier Delivery

June 23, 2014

U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Ms. Kathryn Montague
Registration Manager (PM - 23)

Subject: ZONE HERBICIDE (EPA-Reg.No.74530 - to be assigned)
Application for new product registration

HELM Agro US Inc. herewith submits an application for a new end-use product registration containing the two active ingredients, sulfentrazone and chlorimuron-ethyl. The composition of this product and proposed use directions for ZONE HERBICIDE are similar (see enclosed label) to those of the existing, registered end-use formulation, Authority XL Herbicide (EPA Reg. No. 279-3413). Therefore, this application is considered a "me-too" registration, which only requires data review of the enclosed acute toxicity and Product Chemistry studies. Otherwise the application relies on existing data as indicated on the enclosed Data Matrix and the "Cite-all Option" under the Selective Method.

The ZONE HERBICIDE formulation contains all EPA approved formulation ingredients (40 CFR §180.910 - tolerance exemption when used pre- and post-harvest). The Precautionary Labeling is based on the enclosed acute toxicity data (see also toxicity summary below), following EPA's Label Review Manual and 40 CFR part 156.

The subject application for registration is supported by the enclosed information and administrative materials:

1. EPA Form 8570-1:
Executed "Application for Pesticide Registration" (OPP Identifier # 259973).
2. Bibliography of Submitted Studies
Copy of the Bibliography of Submitted Studies. This provides an index of study titles and references to EPA data requirements by OPPTS Guideline number.
3. Proposed Label
Five copies of the proposed ZONE HERBICIDE Master label.

5. Study Data

Three copies of each acute toxicity study report (total of 9 volumes).

4. Results of Acute Toxicity Data

The results of the six required acute toxicity studies for the subject formulation are presented below (see Table). The results show that ZONE HERBICIDE is of low acute oral, dermal and inhalational toxicity to rats (Category III or IV). It is non-irritating to the rabbit skin, minimally irritating to the eye, and shows no sensitization potential in the guinea pig. Based on these data, ZONE HERBICIDE is classified as a Toxicity Category III product (Signal word "CAUTION"; see also proposed labeling reflecting these results).

Acute Toxicity Data for ZONE HERBICIDE (see submitted study reports)

Guideline #	Study	Results (MRID)	Category
81-1	LD50 Oral Rat (female)	1,750 mg/kg	III
81-2	LD50 Dermal rat	>5,000 mg/kg	IV
81-3	LC50 4h Inhalation-rat	>5.17 mg/l	IV
81-4	Eye Irritation rabbit	minimally irritating (clearing in < 24 h)	IV
81-5	Skin Irritation rabbit	Non-irritating	IV
81-6	Skin Sensitization Guinea Pig (Buehler Method)	Negative (not a Sensitizer)	N/A

5. Confidential Statement of Formula

One copy of the Confidential Statement of Formula (CSF).

7. Certification with Respect to Citation of Generic Data

An executed EPA form 8570-34 with respect to citation of data.

8. Data Matrix (EPA form 8570-35)

One copy of a data matrix of all previously submitted data (including the generic data submitters) in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public Use). Helm is offering to pay data compensation to those registrants appearing on the most recent, published EPA Data Submitters Lists for sulfentrazone and chlorimorfen-ethyl dated March 27, 2014.

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Product(s): ZONE HERBICIDE

EPA Registration No: 74530-to be assigned

Purpose of Submission: Submission of data in support of the application for "me-too" registration of ZONE HERBICIDE

Date of Submission: June 23, 2014

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Product Identity and Composition (Group A Data) Summary of Physical and Chemical Properties (Group B data)	Ceres #140529	830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.1900, 830.6302 through 830.7950	49417901
2 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Enforcement Analytical method for the Determination of Sulfentrazone and Chlorimuron Ethyl by High Performance Liquid Chromatography	Product Safety Labs # 36900 AEM	830.1800	49417902
3 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, and Density/Bulk Density	Product Safety Labs # 36901	830.6302 830.6303 830.6304 830.6314 830.7000 830.7300	49417903

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
4 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Oral Toxicity Study – Up and Down Procedure in Rats	Product Safety Labs # 36880	870.1100	49417904
5 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Dermal Toxicity Study in Rats – Limit Test	Product Safety Labs # 36881	870.1200	49417905
6 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Inhalation Toxicity Study in Rats – Limit Test	Product Safety Labs # 36882	870.1300	49417906
7 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Primary Eye Irritation Study in Rabbits	Product Safety Labs # 36883	870.2400	49417907
8 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Primary Skin Irritation Study in Rabbits	Product Safety Labs # 36884	870.2500	49417908
9 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Local Lymph Node Assay (LLNA) in Mice	Product Safety Labs # 36885	870.2600	49417909



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number
259973

Application for Pesticide - Section I

1. Company/Product Number 74530-XX	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ZONE HERBICIDE	PM# PM 23	
5. Name and Address of Application (Include ZIP Code) HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: F9016 DF (ABN: Authority XL Herbicide); EPA Reg. No. 279-3413

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission - Explain below.	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application of a "me-too" end-use registration containing the active ingredients, sulfentrazone plus chlorimuron-ethyl, which is similar in composition and labeling to Authority XL Herbicide (EPA Reg. No. 279-3413). The sources of both AIs are presently under review for registration. This application only requires reviews of the submitted acute toxicity and product chemistry data (Non-fast track; PRIA EPA # R310, EPA decision review time of 7 months, fee = \$5,048
Contact by EMAIL: bertvolger@comcast.net

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes", Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
--	---	--	---

3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Bert Volger, Ph.D.	Title Agent for HELM Agro US, Inc.	Telephone No. (Include Area Code) Phone: 610-793-3222 Fax: 610-793-1705
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for HELM Agro US, Inc.	6. Date Application Received (Stamped)
4. Typed Name Bert Volger	5. Date 6/23/2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610	EPA Registration Number/File Symbol 74530 - xx
Active Inactive(s) and/or representative test compound(s) Sulfentrazone plus Chlorimuron-ethyl	Date June 23, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, and Terrestrial Non-Food use sites	Product Name ZONE HERBICIDE

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility, i.e., compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to provide such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 6/23/2014	Typed or Printed Name and Title Bert Volger, Agent for Helm Agro US Inc.
---------------	-------------------	---

**HELM AGRO US, INC.**

4042 Park Oaks Blvd., Suite 330

Tampa, FL 33610

Phone: (813) 621-8846

Fax: (813) 621-0763

www.helmagro.com

Via Courier Delivery**June 23, 2014**

U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Ms. Kathryn Montague
Registration Manager (PM - 23)

Subject: ZONE HERBICIDE (EPA-Reg.No.74530 - to be assigned)
Application for new product registration

HELM Agro US Inc. herewith submits an application for a new end-use product registration containing the two active ingredients, sulfentrazone and chlorimuron-ethyl. The composition of this product and proposed use directions for ZONE HERBICIDE are similar (see enclosed label) to those of the existing, registered end-use formulation, Authority XL Herbicide (EPA Reg. No. 279-3413). Therefore, this application is considered a "me-too" registration, which only requires data review of the enclosed acute toxicity and Product Chemistry studies. Otherwise the application relies on existing data as indicated on the enclosed Data Matrix and the "Cite-all Option" under the Selective Method.

The ZONE HERBICIDE formulation contains all EPA approved formulation ingredients (40 CFR §180.910 - tolerance exemption when used pre- and post-harvest). The Precautionary Labeling is based on the enclosed acute toxicity data (see also toxicity summary below), following EPA's Label Review Manual and 40 CFR part 156.

The subject application for registration is supported by the enclosed information and administrative materials:

1. EPA Form 8570-1:
Executed "Application for Pesticide Registration" (OPP Identifier # 259973).
2. Bibliography of Submitted Studies
Copy of the Bibliography of Submitted Studies. This provides an index of study titles and references to EPA data requirements by OPPTS Guideline number.
3. Proposed Label
Five copies of the proposed ZONE HERBICIDE Master label.

5. Study Data

Three copies of each acute toxicity study report (total of 9 volumes).

4. Results of Acute Toxicity Data

The results of the six required acute toxicity studies for the subject formulation are presented below (see Table). The results show that ZONE HERBICIDE is of low acute oral, dermal and inhalational toxicity to rats (Category III or IV). It is non-irritating to the rabbit skin, minimally irritating to the eye, and shows no sensitization potential in the guinea pig. Based on these data, ZONE HERBICIDE is classified as a Toxicity Category III product (Signal word "CAUTION"; see also proposed labeling reflecting these results).

Acute Toxicity Data for ZONE HERBICIDE (see submitted study reports)

Guideline #	Study	Results (MRID)	Category
81-1	LD50 Oral Rat (female)	1,750 mg/kg	III
81-2	LD50 Dermal rat	>5,000 mg/kg	IV
81-3	LC50 4h Inhalation-rat	>5.17 mg/l	IV
81-4	Eye Irritation rabbit	minimally irritating (clearing in < 24 h)	IV
81-5	Skin Irritation rabbit	Non-irritating	IV
81-6	Skin Sensitization Guinea Pig (Buehler Method)	Negative (not a Sensitizer)	N/A

5. Confidential Statement of Formula

One copy of the Confidential Statement of Formula (CSF).

7. Certification with Respect to Citation of Generic Data

An executed EPA form 8570-34 with respect to citation of data.

8. Data Matrix (EPA form 8570-35)

One copy of a data matrix of all previously submitted data (including the generic data submitters) in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public Use). Helm is offering to pay data compensation to those registrants appearing on the most recent, published EPA Data Submitters Lists for sulfentrazone and chlorimorfen-ethyl dated March 27, 2014.

9. Registration Service Fee

Under PRIA II, the subject application should be assigned EPA's Action Code R310: New end-use product, requires data review only of acute toxicity and product chemistry data; 7 months review; \$5,048 fee.

10. Confirmation of PRIA fee payment

Pay.gov Tracking ID: 252T75HO; Agency Tracking ID: 74635387319 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this application for registration of the subject product and the receipt of the stamped, approved label. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,



Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Product(s): ZONE HERBICIDE

EPA Registration No: 74530-to be assigned

Purpose of Submission: Submission of data in support of the application for "me-too" registration of ZONE HERBICIDE

Date of Submission: June 23, 2014

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Product Identity and Composition (Group A Data) Summary of Physical and Chemical Properties (Group B data)	Ceres #140529	830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.1900, 830.6302 through 830.7950	
2 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Enforcement Analytical method for the Determination of Sulfentrazone and Chlorimuron Ethyl by High Performance Liquid Chromatography	Product Safety Labs # 36900 AEM	830.1800	
3 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, and Density/Bulk Density	Product Safety Labs # 36901	830.6302 830.6303 830.6304 830.6314 830.7000 830.7300	

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
4 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Oral Toxicity Study – Up and Down Procedure in Rats	Product Safety Labs # 36880	870.1100	
5 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Dermal Toxicity Study in Rats – Limit Test	Product Safety Labs # 36881	870.1200	
6 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Acute Inhalation Toxicity Study in Rats – Limit Test	Product Safety Labs # 36882	870.1300	
7 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Primary Eye Irritation Study in Rabbits	Product Safety Labs # 36883	870.2400	
8 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Primary Skin Irritation Study in Rabbits	Product Safety Labs # 36884	870.2500	
9 of 9	ZONE HERBICIDE (Sulfentrazone+Chlorimuron Ethyl 62.2+7.8 WG) Local Lymph Node Assay (LLNA) in Mice	Product Safety Labs # 36885	870.2600	



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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: July 1, 2014

EPA Reg No./File Symbol: 74530-xx

Page 1 of 4

Applicant's/Registrant's Name & Address: HELM AGRO US, Inc.,
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Product:
ZONE HERBICIDE

Ingredients: Sulfentrazone plus Chlorimuron-ethyl

Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.		Not required for end-use product
			Helm Agro US, Inc.	OWN	See submitted CSF
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.		Not required for this end-use product
			Helm Agro US, Inc.	OWN	Submitted with subject application
			Helm Agro US, Inc.		Not required for end-use product
			Helm Agro US, Inc.		Not required for end-use product
			Helm Agro US, Inc.		Not required for end-use product

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



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DATA MATRIX

Date: July 1, 2014	EPA Reg No./File Symbol: 74530-xx	Page 2 of 4
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610	Product: ZONE HERBICIDE	

Ingredient: Sulfentrazone plus Chlorimuron-ethyl

Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
			Helm Agro US, Inc.		Not required for end-use product
			Helm Agro US	OWN	Submitted with subject application
			Helm Agro US		Not required for this end-use product
			Helm Agro US	OWN	Submitted with subject application
			Helm Agro US	OWN	Not flammable; solid product does not contain any combustible liquids
			Helm Agro US	OWN	Not explosive based on its chemical/ physical properties, product does reveal bond groupings to be explosive
			Helm Agro US	OWN	New study under way
					Not required for this end-use product.
			Helm Agro US		Not required as this product is being diluted in water, not intended to be mixed and applied in petroleum solvents
			Helm Agro US	OWN	New study under way
			Helm Agro US		Product is not for use in/on/around electrical equipment
			Helm Agro US	OWN	Submitted with subject application
			Helm Agro US	OWN	Submitted with subject application
			Helm Agro US	OWN	Submitted with subject application

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DATA MATRIX

Date: July 1, 2014		EPA Reg No./File Symbol: 74530-xx		Page 3 of 4	
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610		Product: ZONE HERBICIDE			
Ingredient: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	Submitted with subject application
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	Submitted with subject application
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	Submitted with subject application
Helm Agro US Inc. is making offers-to-pay to the following companies listed on EPA's Data Submitters list as of March 27, 2014.		EPA Company No.			
[REDACTED]	[REDACTED]	[REDACTED]	FMC Corporation	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	E.I. DuPont De Nemours and Co.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	PBI Gordon Corp.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Chemsico	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Spray Drift Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Agricultural Reentry Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Tagros Chemicals India Ltd.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	FIFRA Endangered Species Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Agricultural Handlers Exposure Task Force	PAY	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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DATA MATRIX

Date: July 1, 2014		EPA Reg No./File Symbol: 74530-xx		Page 4 of 4	
Applicant's/Registrant's Name & Address: HELM AGRO US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610		Product: ZONE HERBICIDE			
Ingredient: Sulfentrazone plus Chlorimuron-ethyl					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Summit Agro North America Holding Corp	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Summit Agro USA LLC	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	FMC Corporation	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	E.I. DuPont De Nemours and Co.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Nufarm Limited	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Valent USA Corp.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Spray Drift Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Nufarm Inc.	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Agricultural Reentry Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	FIFRA Endangered Species Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Agricultural Handlers Exposure Task Force	PAY	
[REDACTED]	[REDACTED]	[REDACTED]	Sharda Cropchem Limited	PAY	
Signature: <i>Bert Volger</i>			Name and Title: Bert Volger, Ph.D. Agent for HELM AGRO US Inc.		Date: July 1, 2014

21-Day Screen Completed by
Contractor

21-Day Expires on 7-16-14

Jacket # 74530 - AN
MRID# 494179

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN Setta

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6-25-14

Experts In-Processing Signature: B.B.

Date 6-27-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74530-AN</u>		EPA Receipt Date: <u>6-25-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * Studies submitted passed PRN 11-03 review.
- * inerts approved for food use under 40 CFR 180.920, pre-harvest application to growing crops.
- * registrant contacted 7/1/14 due to missing guidelines:
 - 830.1650 - Description of Formulation Process
 - 830.6321 - Dielectric Breakdown Voltage.
- * registrant provided corrections on 7/1/14.
- * jacket passed.

MRID: 494179

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [Inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Burkhart, Kira

From: Burkhart, Kira
Sent: Tuesday, July 01, 2014 2:04 PM
To: 'Bert Volger'
Cc: Ashe, Anthony; Correa, Leah
Subject: RE: Submission to EPA: Zone Herbicide (EPA Reg. # 74530-AN)

Hi Bert,

Thank you for your prompt response. I'll go ahead and forward the application to the PM for further review.

Kind Regards,

Kira Burkhart

Contractor, US EPA
2777 S. Crystal Drive, S-4816
Arlington, VA 22202
Ph: (703) 347-0215
Email: burkhart.kira@epa.gov

From: Bert Volger [<mailto:bertvolger@comcast.net>]
Sent: Tuesday, July 01, 2014 1:58 PM
To: Burkhart, Kira
Cc: Ashe, Anthony; Correa, Leah
Subject: RE: Submission to EPA: Zone Herbicide (EPA Reg. # 74530-AN)

Hi Kira,

addressing the identified deficiencies, attached you will find the two revised Data Matrix documents (Agency and Public File copy).

Please let me know, if you have any further comments or questions.

Thanks,
Bert

Agent for Helm Agro US Inc.
c/o Ceres International LLC
1087 Heartsease Drive
West Chester, PA 19382
Ph. 610-793-3222
bertvolger@ceresinternational.com

From: Burkhart, Kira [<mailto:Burkhart.Kira@epa.gov>]
Sent: Tuesday, July 01, 2014 11:21 AM
To: bertvolger@comcast.net

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis	✓					
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explodability	✓					
830.6317	Storage stability	✓					
830.6319	Miscibility	✓					
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage	✓					
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	✓			
870.1200	Acute Dermal (LD50)	✓			
870.1300	Acute Inhalation (LC50)	✓			
870.2400	Acute Eye Irritation	✓			
870.2500	Acute Dermal Irritation	✓			
870.2600	Dermal Sensitization	✓			

Efficacy - which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					N/A
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					N/A
810.3300	Treatments to Control Pests of Humans and Pets					N/A
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					N/A
810.3500	Premises Treatments					N/A
810.3600	Structural Treatments					N/A
810.3800	Methods for Efficacy Testing of Termite Baits					N/A



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 27, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-492572
EPA File Symbol or Registration Number: 74530-AN
Product Name: ZONE HERBICIDE
EPA Receipt Date: 25-Jun-2014
EPA Company Number: 74530
Company Name: HELM AGRO US, INC.

BERT VOLGER, PH.D.
CERES INTERNATIONAL LLC
HELM AGRO US, INC.
1087 HEARTSEASE DRIVE
WEST CHESTER, PA 19382-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S); INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS; REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY; INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:: PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY; CHILD RESISTANT PACKAGING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,


Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

M
{954110c~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

23

Receipt No.

S-

954110

EPA File Symbol/Reg. No.

74530-AN

Pin-Punch Date:

6/25/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 5048.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Maggie Ruck

Date: 6/27/14

Remarks:

SIMILARITY CLINIC - SIMILAR TO 279-3413

Receipt for Section 3

S: 954110 Milestone Email: [Redacted]

Regulatory Type: Product Registration - Section 3 [v]
Application Type: New Registration [v]

Company: 74530 HELM AGRO US, INC. [V]

Risk Manager: Registration Division, Risk Management Team 23 [v]

Product #: 74530-AN Product Name: ZONE HERBICIDE

Override: [v]
Me Too Section3: [v] Me Too Product Name: [v]

Application Date: 23-Jun-2014 [v] OPP Rec'd Date: 25-Jun-2014 [v]
Front End Date: 26-Jun-2014 [v] Risk Manager Send Date: [v]
FFS Due Date: [v] Negotiated Due Date: [v]
OPP Target Date: [v]

Fast Track: [v] New Ingredient: [v]

Receipt Description:
Application for new product registration.

Form A: [v] Signature Date: [v] Form B: [v] Signature Date: [v]

Resolution: [v] Yes [v] No
Fee For Service: [v] Yes [v] No
Billable: [v] Yes [v] No

Print Letter
Enter More Information
Tracking

Receipt Content
Study
CSF
View/Edit

New Ingredient
Request Date: [v]
New Ingredient
Received Date: [v]

Online Payment**Step 3: Confirm Payment**

1 | 2 | 3

Thank you.**Your transaction has been successfully completed.****Pay.gov Tracking Information****Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 25G9R8DM**Agency Tracking ID:** 74635387319**Transaction Date and Time:** 06/20/2014 11:39 EDT**Payment Summary****Address Information**

Account Holder Name: Bert Volger
1087 Heartsease
Billing Address: Drive
Billing Address 2:
City: West Chester
State / Province: PA
Zip / Postal Code: 19382
Country: USA

Account Information

Card Type: Visa
Card Number: *****6411
Decision Number:
Registration Number:
Company Name: Helm Agro US
Company Number: 74530
Action Code: R310

Payment Information

Payment Amount: \$5,048.00
Transaction Date and Time: 06/20/2014
and Time: 11:39 EDT

FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.

74530-AN

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUN 25 2014		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

